OCT 23 2006

K062446

The introducer sheath consists of 2 pieces of ETFE tubing – a long segment and a short tip segment. The band is sandwiched between the two segments and radiofrequency (RF) welding is used to fuse the two segments together. The band is completely encapsulated within the tubing wall.

The PINNACLE R/O II HiFlow Introducer Sheath is used to facilitate placement of a catheter through the skin into a vein or artery. A Mini Guide Wire (with Inserter) may be included with the device. The Inserter does not contact blood and is used strictly for guiding the Guide Wire into a cannula or Introducer.

The Mini Guide Wire is inserted through a cannula placed in the patient's blood vessel. The PINNACLE R/O II HiFlow Introducer Sheath is then inserted over the Mini Guide Wire and into the blood vessel. The Mini Guide Wire is then withdrawn from the vessel. The Dilator maintains the integrity of the Sheath and dilates the blood vessel while the Introducer Sheath is being placed into the vessel. The Dilator can be removed and an appropriate catheter can then be inserted. The RADIFOCUS Obturator is an accessory device which creates an occlusion when inserted into the Sheath. The Obturator also provides support to the indwelling Sheath after the catheter is removed.

The Sheath, Dilator and Obturator contain bismuth, making these devices slightly visible under fluoroscopy.

E. PRINCIPLE OF OPERATION / TECHNOLOGY

The Pinnacle® ROII HiFlow Introducer Sheaths operated manually or by a manual process.

F. DESIGN / MATERIALS

The Pinnacle® ROII HiFlow Introducer Sheath uses similar materials as the predicate device. Differences in materials between the two devices do not raise any new issues of safety and effectiveness.

G. SPECIFICATIONS

Sheath Sizes:	6Fr. (0.087" nominal lumen size) 7Fr. (0.100" nominal lumen size) 8Fr. (0.115" nominal lumen size)
Sheath Length:	4-110 cm
Dilator Length:	5-110 cm
Guide Wire OD:	0.021" – 0.038"

H. PERFORMANCE

The performance of the Pinnacle® ROII HiFlow Introducer Sheath is substantially equivalent to the performance of the predicate device K003424. The equivalence was shown through bench testing.

I. ADDITIONAL SAFETY INFORMATION

Sterilization conditions have been validated in accordance with ANSI / AAMI / ISO 11135-1994 to provide a Sterility Assurance Level of 10^{-6}.

Blood contacting materials were tested in accordance with the test recommendations in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part I: Evaluation and Testing." The Pinnacle® ROII HiFlow Introducer Sheath is categorized as "Externally Communicating Device, Circulating Blood, Prolonged Contact (24hrs to 30 days)". The blood contacting materials were found to be biocompatible.

Expiration dating for the Pinnacle® ROII HiFlow Introducer Sheath will be 30 months.

J. SUBSTANTIAL EQUIVALENCE

The Pinnacle® ROII HiFlow Introducer Sheath submitted in this 510(k) is substantially equivalent in intended use, design, principle of operation / technology, materials and performance to the Pinnacle® ROII (K003424), which is also manufactured by Terumo Medical Corporation. Differences between the devices do not raise any issues of safety or effectiveness.

K. SUBMITTER INFORMATION

Name and Address

Terumo Medical Corporation
950 Elkton Blvd.
Elkton, MD 21921

Contact Person

Mr. Mark Unterreiner
Sr. Regulatory Affairs Specialist
Ph: 410-392-7213
Fax: 410-398-6079
Email: mark.unterreiner@terumomedical.com

Date Prepared

August18, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 3 2006

Terumo Medical Corporation
c/o Mr. Mark Unterreiner
Sr. Regulatory Affairs Specialist
125 Blue Ball Road
Elkton, MD 21921

Re: K062446
Pinnacle® RO11 HiFlow Introducer Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: II
Product Code: DYB
Dated: September 25, 2006
Received: September 26, 2006

Dear Mr. Unterreiner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Lochner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062446

Device Name: Pinnacle® ROII HiFlow Introducer Sheath

Indications For Use:

The Pinnacle® ROII HiFlow Introducer Sheath is used to facilitate placing a catheter through the skin into a vein or artery. The Mini Guide Wire is an accessory device which is used for placement of the sheath into the vein or artery. The RADIFOCUS Obturator is also an accessory device which is used by placing it into the sheath to create an occlusion and further provide support to the wall of the indwelling sheath while it remains in place within the vein or artery after removal of a catheter.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062446